

Application No. : 09/706,965
Amdt. Dated : May 13, 2004
Reply to O.A. of : March 16, 2004

REMARKS

The Applicants thank the Examiner for his careful examination of the present application. By way of summary, Claims 1 and 12-24 were pending in this application. In the present amendment, the Applicants have amended Claims 17 and 23-24. Accordingly, Claims 1 and 12-24 are pending for consideration.

The Present After-Final Amendment Should Be Entered

The Applicants respectfully submit that the amendments made herein to Claims 17 and 23-24, do not raise new issues and should not require a new search because of similarities to elements in non-amended Claim 1. For example, the recitation of a light source capable of irradiating body tissue with light of wavelengths sensitive to at least glucose has been present in this application in Claim 1 since February 2003 and through 3 Office Actions. Also, the recitation of blood volume modulation that does not substantially affect optical properties has been present in Claim 1 since the filing of the present Request for Continued Examination. Accordingly, the Applicants submit that the arguments and amendments presented herein consolidate and clarify issues for appeal. Therefore, the Applicants respectfully request that the Examiner enter the present Amendment and consider the patentability of the pending claims in view of the following arguments.

Rejection Of Claims 17-18, 20-21 and 23-24 Under 35 U.S.C. § 102(b)

The Office Action rejected Claims 17-18, 20-21 and 23-24 under 35 U.S.C. § 102(b) as being anticipated by U.S. patent no. 4,883,055, issued to Merrick (the Merrick patent). The Applicants respectfully traverse this rejection because the Merrick patent fails to identically teach every element of Claims 17-18, 20-21 and 23-24. See M.P.E.P. § 2131 (stating that in order to anticipate a claim, a prior art reference must identically teach every element of the claim).

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Amended independent Claim 17, recites, among other things,

Claim 17. A system . . . comprising:

- a light source configured to irradiate a fleshy medium . . . wherein the irradiation includes radiation at a plurality of wavelengths selected for attenuation sensitivity to at least one of a plurality of blood constituent concentrations including a glucose concentration;

- an active pulse inducement device configured to induce at a location other than the test site a change in a volume of fluid in the fleshy medium, thereby reducing variations in optical properties of the fleshy medium . . . ;

- an optical detector . . . ; and

- a signal processor

Moreover, amended independent Claims 23-24 recite, among other things,

Claim 23. A system . . . comprising:

- an input which accepts a signal output from an optical detector positioned to detect light at a first area which has been attenuated by a fleshy medium of a living subject, said signal including effects of a non-natural active change in a volume of fluid in the fleshy medium, said non-natural active change being induced at a second area on the fleshy medium different from the first area at a level that does not cause significant variations in the optical properties of the first area, wherein the light comprises a plurality of wavelengths, each wavelength selected for attenuation sensitivity to at least one of a plurality of constituent concentrations, said plurality of constituent concentrations including a glucose concentration; and

- a signal processor

Claim 24. A sensor and inducement system . . . comprising:

- a light source configured to irradiate a fleshy medium . . . at a plurality of wavelengths selected for attenuation sensitivity to at least one of a plurality of blood constituent concentrations including a glucose concentration;

- an active pulse inducement device configured to induce at a location other than the test site a change in a volume of fluid in the fleshy medium, thereby reducing variations in optical properties of the fleshy medium . . . ; and

- an optical detector

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As discussed in the Applicants February 10, 2003 Amendment, the Merrick patent discloses a system for measuring only one characteristic of blood, namely, oxygen saturation in arterial blood. Merrick's light source is limited to that one characteristic, hemoglobin. Accordingly, the Merrick patent fails to identically teach every element of independent Claims 17 or 23-24. Therefore, the Applicants respectfully request withdrawal of the rejections based on anticipation by the Merrick patent.

Claims 18 and 20-21, which depend from Claim 17, are believed to be patentable for the same reasons articulated above with respect to Claim 17, and because of the additional features recited therein.

Rejection Of Claims 17, 21 and 23-24 Under 35 U.S.C. § 102(b)

The Office Action also rejected Claims 17, 21 and 23-24 under 35 U.S.C. § 102(b) as being anticipated by U.S. patent no. 4,927,264, issued to Shiga et al. (the Shiga patent). The Applicants respectfully traverse this rejection because the Shiga patent fails to identically teach every element of Claims 17, 21 and 23-24. M.P.E.P. § 2131.

Similar to the Merrick patent, the Shiga patent discloses a system for measuring oxygen saturation. The Shiga patent focuses on determining saturation for venous blood, as opposed to arterial blood. While the Shiga patent discusses another blood constituent, e.g., density, such constituents still focus on the measurement of hemoglobin, while remaining void of any suggestion or inference as to glucose. Accordingly, the Shiga patent also fails to identically teach every element of independent Claims 17 or 23-24. Therefore, the Applicants respectfully request withdrawal of the rejections based on anticipation by the Shiga patent.

Claim 21, which depends from Claim 17, is believed to be patentable for the same reasons articulated above with respect to Claim 17, and because of the additional features recited therein.

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Rejection Of Claims 1, 12 and 15 Under 35 U.S.C. § 103(a)

The Office Action rejected Claims 1, 12, and 15 under 35 U.S.C. § 103 as being unpatentable over U.S. patent no. 5,372,135, issued to Mendelson et al. (the Mendelson patent), in view of U.S. patent no. 5,007,423, issued to Branstetter et al. (the Branstetter patent). The Applicants respectfully traverse this rejection because the Mendelson patent, alone or in combination with the Branstetter patent, fails to teach or suggest the elements of the claims. See M.P.E.P. § 2143 (stating that in order to establish a *prima facie* case of obviousness for a claim, the prior art references must teach or suggest all the claim limitations).

Independent Claim 1, recites, among other things,

Claim 1. A system for non-invasively monitoring concentrations of blood constituents in a living subject, said system comprising:

a light source . . . ;

an active pulse inducement device which causes a periodic change in a volume of blood in the fleshy medium with the level of inducement below a level that causes significant variations in the optical properties of the fleshy medium;

an optical detector . . . ; and

a signal processor

In the Applicants' January 8, 2004 Amendment, the Applicants argued the ineffectiveness of the Mendelson patent as an anticipatory reference because among other things, it fails to teach or suggest causing a periodic change in a volume of blood in the fleshy medium with the level of inducement below a level that causes significant variations in the optical properties of the fleshy medium. For example, the Applicants argued:

Movement of the fleshy medium in the test area can cause changes in the optical path length of the medium, resulting in optical scattering and other sources of noise that can distort the signals due to changes in fluid volume flow. The advantage of reducing this movement in the test area is that it correspondingly reduces the noise in the detected signal by isolating the variations due to varying fluid volume flow. Movement can be reduced by inducing the pulse at a location distal [or proximal] from the area receiving the incident light and by using gentle pressure. Mendelson disregards the important considerations

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above and the deleterious effects of causing excess changes in the optical path length of the fleshy medium.

In response, the present Office Action asserts that the Mendelson patent teaches modulation of blood volume can be accomplished by "methods other than pressure." The Office Action asserts that one of ordinary skill in the art at the time of the invention would be motivated to seek out a solution from the teachings of the Branstetter patent, i.e., that temperature can be used to increase blood flow. The Office Action then combines these two allegations in its case of obviousness against independent Claim 1, further alleging that an artisan would be motivated to use Branstetter's temperature as the modulation technique taught by the Mendelson patent.

However, such allegations fail for at least two specific reasons. First, as stated in the January 8, 2004 Amendment, the Mendelson patent teaches and suggests only modulation through a physical clamp 26 placed at the measurement site. The specific citation used in the Office Action to "imply" that modulation can occur "in a number of ways," fails to account for the examples immediately following that recitation that provide insight into the Mendelson "ways" modulation can occur, i.e., that the clamp 26 can be placed at different measurement sites (See col 4:34-37). Thus, the Mendelson patent provides no implication of different clamps and certainly no implication of using temperature for modulation. In contrast, the source of the teaching for using temperature for modulation appears to have improperly been taken from the Applicants disclosure. See page 6, line 35 and page 11, lines 26-30.

Second, even if the Mendelson patent could be interpreted to imply other modulation techniques, which it cannot, a skilled artisan would not look to the Branstetter patent for modulation using temperature. For example, the Branstetter patent teaches a heat source 32 used to maintain tissue at a predetermined temperature, such as a normal core body temperature of 37° C. See Abstr. lines 8-9; cols. 2:33-47; 3:32-33; 4:5-10 (explaining Branstetter's desire to maintain a constant temperature). Thus, the structures of the Branstetter patent focus on obtaining and

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sustaining a constant temperature, which is just the opposite of teaching or suggesting the modulation of temperature.

Based on the foregoing, the Mendelson patent alone fails to teach or suggest modulation of blood volume that does not cause significant variations in the optical properties of body tissue. Moreover, even if Mendelson could be combined with Branstetter, which it cannot, the combination fails to teach or suggest modulation through temperature, let alone teaching or suggesting the claimed modulation. Accordingly, the Applicants submit that the Mendelson patent, alone or in combination with the Branstetter patent, fails to teach or suggest all the claim limitations, and therefore, fails to establish a *prima facie* case of obviousness against independent Claim 1. Therefore, the Applicants respectfully request withdrawal of the rejection thereof.

The Applicants also submit that Claims 12 and 15, which depend from Claim 1, are patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

Rejection Of Claims 13 Under 35 U.S.C. § 103(a)

The Office Action rejected Claim 13 under 35 U.S.C. § 103 as being unpatentable over the Mendelson patent in view of the Branstetter patent and the Merrick patent. The Applicants respectfully traverse this rejection because the Mendelson, Branstetter, and Merrick patents, alone or in combination with one another, fail to teach or suggest all the elements of the claims. See M.P.E.P. § 2143.

As stated in the foregoing, the Mendelson patent, alone or in combination with the Branstetter patent fail to teach or suggest the recited elements of independent Claim 1. Even assuming for the sake of argument that the Merrick patent can be properly combined with the Mendelson patent or the combination of the Mendelson patent and the Branstetter patent, which it cannot, the Applicants assert that such combination still fails to teach or suggest modulation of blood volume that does not cause significant variations in the optical properties of body tissue. Accordingly, the Applicants submit that the Mendelson patent, alone or in combination with the

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Branstetter and Merrick patents, fails to teach or suggest all the claim limitations, and therefore fails to establish a *prima facie* case of obviousness against independent Claim 1. Thus, the foregoing combination also fails to render obvious dependent Claim 13, because of its dependency on Claim 1 and because of the additional features recited therein. Therefore, the Applicants respectfully request withdrawal of the rejection thereof.

Rejection Of Claims 1, 14, 16 and 19 Under 35 U.S.C. § 103(a)

The Office Action rejected Claims 1, 14, 16 and 19 under 35 U.S.C. § 103 as being unpatentable over the Shiga patent in view of the Mendelson patent. The Applicants respectfully traverse this rejection because the Shiga patent, alone or in combination with the Mendelson patent, fails to teach or suggest all the elements of the claims. See M.P.E.P. § 2143.

The Shiga patent discloses a system for determining, among other things, the oxygen saturation of venous blood, apparently because venous saturation compared with arterial saturation provides insights into the tissue being measured. See col. 2:32-36. However, according to the Shiga patent, venous blood is rarely of sufficient volume to absorb enough light to make the attenuation thereof analyzable. Therefore, the Shiga patent discloses a system for completely occluding venous blood flow without occluding arterial blood flow. This way, the blood pools in the veins and according to the Shiga patent, because of the veins increase blood volume, the saturation in the veins becomes a larger part of the attenuated light detected by the Shiga oximeter. While Shiga argues that such techniques are advantageous in the determination of venous saturation, Shiga's dramatic perturbation that causes occlusion of the venous system dramatically changes the optical properties at the test site. This exact argument of occlusion was presented to the Patent Office in a parent case (U.S. pat. no. 5,638,816) that relied on Shiga and Merrick in 1995.

In short, similar to the discussion of the Mendelson patent above, the Shiga patent fails to teach or suggest the modulation of blood volume that does not cause significant variations in the optical properties of body tissue. Accordingly, the Applicants

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submit that the Shiga patent, alone or in combination with the Mendelson, fails to teach or suggest all the claim limitations, and therefore fails to establish a *prima facie* case of obviousness against independent Claim 1. Therefore, the Applicants respectfully request withdrawal of the rejection thereof.

The Applicants also assert that Claims 14 and 16, which depend from Claim 1, are patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein. Moreover, as stated in the foregoing, the Shiga patent fails alone to anticipate independent Claim 17, and the Applicants also submit that the Shiga patent, alone or in combination with the Mendelson, fails to teach or suggest all the limitations of Claim 17, and therefore fails to establish a *prima facie* case of obviousness against independent Claim 17. Thus, the foregoing combination also fails to render obvious dependent Claim 19, because of its dependency on Claim 17 and because of the additional features recited therein. Therefore, the Applicants respectfully request withdrawal of the rejection thereof.

Rejection Of Claims 22 Under 35 U.S.C. § 103(a)

The Office Action rejected Claim 22 under 35 U.S.C. § 102(b) as being anticipated by the Merrick patent in view of the Mendelson patent and the Branstetter patent. The Applicants assume that this rejection was intended as a 103(a) rejection, and the recitation of "102(b)" amounts to a typographical error. The following discusses the merits of the rejection based on that assumption.

The Applicants respectfully traverse this rejection because the Merrick Mendelson, and Branstetter patents, alone or in combination with one another, fail to teach or suggest all the elements of the claims. See M.P.E.P. § 2143.

As stated in the foregoing, the Merrick patent fails to anticipate independent Claim 17. Even assuming that the Merrick patent can be properly combined with the Mendelson patent, or the combination of the Mendelson patent and the Branstetter patent, which it cannot, the Applicant asserts that such combination still fails to teach or suggest modulation of blood volume at a test site while reducing variation in body tissue of the test site. Accordingly, the Applicants submit that the Merrick patent, alone or in

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combination with the Branstetter and Mendelson patents, fails to teach or suggest all the claim limitations, and therefore fail to establish a *prima facie* case of obviousness against independent Claim 17. Thus, the foregoing combination also fails to render obvious dependent Claim 22, because of its dependency and because of the additional features recited therein. Therefore, the Applicants respectfully request withdrawal of the rejection thereof.

Traversal of Rejection of Claim 15 in January 8, 2004 Amendment

The Office Action alleges that the Applicants failed to traverse the rejection of Claim 15 in their response on January 8, 2004. The Applicants respectfully disagree. In the January 8, 2004 Amendment, the Applicants properly traversed the rejection, stating,

Claims 12-15, which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein (emphasis added).

Request For Telephone Interview

In view of the forgoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Applicants' undersigned attorney of record hereby formally requests a telephone interview with the Examiner. The Applicants' attorney can be reached at (949) 721-2946 or at the number listed below.

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In addition, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: 

John M. Grover
Registration No. 42,610
Attorney of Record
Customer No. 20,995
(949) 760-0404

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